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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,464

02/17/2004

Srinivasa Madhyastha

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06/21/2006

MERCHANT & GOULD PC

P.O. BOX 2903

MINNEAPOLIS, MN 55402-0903

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/781,464	Applicant(s) MADHYASTHA, SRINIVASA	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14 and 35-46 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 12-14 and 35-41 is/are rejected.
 7) ☒ Claim(s) 42-46 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 09 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 12-14 and 35-46 are pending.

Applicant's amendment filed April 10, 2006 is acknowledged, and applicants' response has been fully considered. Claim 12 has been amended, and new claims 35-46 have been added. Therefore, claims 12-14 and 35-46 are examined.

2. Applicant's submission of application data sheet (ADS) filed April 10, 2006 is acknowledged.

Withdrawn-Claim Rejections - 35 U.S.C. § 102

3. The previous rejection of claims 12 and 14 under 35 U.S.C. § 102(e) as being anticipated by Nemori et al. (U.S. Patent 2003/0148399), is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 5 in the amendment filed April 10, 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Charter et al. (US 2002/0001582, published Jan. 3, 2002) taken with Johansen (WO 96/06532).

Charter et al. discloses a fungicidal composition comprising one of more "active ingredients" or "fungicides" which is selected from the group of avidin, lysozyme,

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ovotransferrin, chicken immunoglobulins, chitosan, polylysine, protamine, nisen, EDTA, rosemary, cinnamaldehyde, allicin and eugenol (paragraph [0073]; claim 12 and 14); and a method of treating plants, plant tissues and seeds that are infected with fungi, the method comprising contacting the plants, plant tissues and seeds with avidin in an effective amount to inhibiting fungi, and the composition may further comprise an effective amount of a compound selected from the group consisting of lysozyme, ovotransferrin, chicken immunoglobulins, chitosan, polylysine, protamine, nisen, EDTA, rosemary, cinnamaldehyde, allicin and eugenol (paragraph [0045]; claim 13). While Charter *et al.* teach the use of protamine, the reference does not specifically teach the use of protamine sulfate in the composition.

Johansen discloses a bacteriocidal or fungicidal composition comprising a basic protein in combination with a cell-wall degrading enzyme or an oxidoreductase, where either protamine or protamine sulfate can be used as the basic protein (page 3, line 11-page 4, line 15).

At the time of invention was made, it would have been obvious that one of ordinary skill in the art is motivated to combine the two references to use protamine sulfate as the basic protein as taught by Johansen in preparing a fungicidal composition comprising one or more active ingredients including ovotransferrin and EDTA as taught by Charter *et al.* because both protamine and protamine sulfate exhibit optimum antimicrobial effect at alkaline pH, thus making such proteins suitable for incorporation in a composition for cleaning purposes (page 4, line 1-5 of WO 96/06532), which indicates either protamine or protamine sulfate has the same antimicrobial effect. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Response to Arguments

Applicants indicate Charter *et al.* disclose a composition for inhibition of growth of fungi or protists on plants and plant tissues; and WO 96/06532 discloses a composition capable of killing microbial cells or inhibiting growth of microbial cells for use as a cleaning or detergent composition, while the instant invention is compositions that inhibit bacteria in a biofilm.

Applicants assert that antifungal agents are not reasonably pertinent to antibacterial agents due to the complex differences between the two microorganisms, due to the differences in cell structure, there is no expectation that an antimicrobial that works against fungi would inhibit bacteria in a biofilm. Applicants further assert that there is no motivation to combine these two references since the Johansen reference is directed to a completely different solution to a completely different problem than the Charter *et al.* reference. Furthermore, the applicant is the first to show an unexpected enhanced effect for inhibiting bacterial biofilm on devices by the use of the selected claimed compositions (see, for example, Figures 10 and 12). There is absolutely nothing in Charter *et al.* nor Johansen that would suggest an enhanced effect for the combination of ovotransferin, protamine sulfate, and EDTA, or ovotransferrin and protamine sulfate, or ovotransferlin and EDTA. Therefore, in view of the foregoing, withdrawal of the rejection is requested (pages 5-8 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. Charter *et al.* discloses a fungicidal composition can be a composition comprising ovotransferrin, protamine and/or EDTA, which are the required components in the claimed composition. Although Charter *et al.* indicate the use of protamine instead of protamine sulfate, it is known that protamine is a basic protein, and protamine sulfate is merely a salt form of protamine. Johansen teaches that either protamine (base form) or

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protamine sulfate (salt form) can be used since they are the same protein. Since Charter *et al.* have already disclosed the required components in the composition, the use of the secondary reference (i.e., Johansen) merely indicates protamine and protamine sulfate can be substituted with each other, which is the motivation to combine the two references. Since the claimed invention is directed to a product claim, where the term “for inhibiting bacterial biofilm” is an intended use, which does not have weight in the claim. Although the specification has shown an unexpected enhanced effect for inhibiting bacterial biofilm on devices by the use of the claimed compositions, this effect is not recited in the claimed composition. Since the combination of Charter *et al.* and Johansen teaches the same composition as the claimed invention, the rejection maintained.

5. Claims 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willcox *et al.* (CA 2, 284,364, published April 2, 2002) taken with Tomita *et al.* (EP 629347, published at December 21, 1994).

Willcox *et al.* disclose an antimicrobial agent such as lactoferrin is used to coat a surface of a biomedical device, where the biomedical device is meant any device designed to be used in or on either or both human tissue or fluid, e.g., stents, implants, catheters and ophthalmic lenses (page 2; claims 37-41), and wherein the surface on the biomedical device is a polymer of ethylene or propylene, polyurethanes, polyesters and mixtures thereof, or silicones containing hydrogels (page 4, lines 15-29; claim 36). However, Willcox *et al.* do not teach the use of ovotransferrin, protamine sulfate and EDTA; ovotransferrin and protamine sulfate; or ovotransferrin and EDTA in the coatings.

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Tomita *et al.* disclose an antimicrobial agent comprising lactoferrin hydrolysates, one or more antimicrobial peptides from lactoferrin; and one of more compounds selected from the group consisting of metal-chelating protein (e.g., lactoferrin, transferrin, conalbumin; page 5, lines 36-38), tocopherol, EDTA or a salt thereof, or others (page 4, lines 11-19). The reference also teaches the antimicrobial agent can be used for treatment of any products or materials thereof, e.g., dentifrices, diapers or others (page 6, lines 23-42).

At the time of invention was made, it would have been obvious that one of ordinary skill in the art is motivated to combine the two references to use the antimicrobial agent containing lactoferrin, lactoferrin peptides, conalbumin and EDTA as taught by Tomita *et al.* in preparing an antimicrobial coating as taught by Willcox *et al.* (claim 35) because the antimicrobial agent taught by Tomita *et al.* contains additional antimicrobial compounds such as EDTA and lactoferrin peptides, conalbumin in addition to lactoferrin; further, the antimicrobial agent is suggested to treat other products. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Claim Objections

6. Claims 42-46 are objected to because the claims are dependent from a rejected claim, claim 12.

Conclusion

7. Claims 12-14 and 35-41 are rejected; and claims 42-46 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

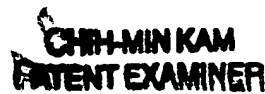
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Chih-Min Kam, Ph. D.

Primary Patent Examiner

A handwritten signature in black ink, appearing to be 'Chih-Min Kam', with a long horizontal stroke extending to the right.A black and white stamp. The top line reads 'CHIH-MIN KAM' and the bottom line reads 'PATENT EXAMINER' in a bold, sans-serif font.

CMK

June 19, 2006